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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/479,252	01/07/00	ASHKENAZI	A P0978p5

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HM22/0516

EXAMINER

BUNNER, B

ART UNIT	PAPER NUMBER
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1647

DATE MAILED:

05/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/479,252

Applicant(s)

ASHKENAZI ET AL.

Examiner

Bridget E. Bunner

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1 and 3-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3-6, 18-19, 22, and 25 drawn to an isolated soluble Apo-2 ligand polypeptide comprising amino acid residues 91-281 of SEQ ID NO: 1, classified in class 530, subclass 350.
 - II. Claims 1 and 7-8, drawn to an isolated Apo-2 ligand polypeptide wherein the polypeptide is linked to polyethylene glycol, classified in class 530, subclass 387.1.
 - III. Claims 1 and 9-10, drawn to an isolated chimeric Apo-2 ligand polypeptide fused to a heterologous tag polypeptide sequences, classified in class 530, subclass 387.3.
 - IV. Claims 11-17, drawn to an isolated nucleic acid comprising DNA encoding the Apo-2 ligand polypeptide, a vector and host cell comprising the nucleic acid, and a method of producing the Apo-2 ligand polypeptide, classified in class 536, subclass 23.1.
 - V. Claims 20-21, 23-24, and 26 drawn to a method of inducing apoptosis in mammalian cancer cells comprising exposing mammalian cancer cells to an effective amount of the Apo-2 ligand polypeptide, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

- a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the proteins of Groups I-III can be prepared by processes which are materially different from recombinant DNA expression of Group IV, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group IV can be used other than to make the protein of Group I, such as

in gene therapy or as a probe in nucleic acid hybridization assays. Inventions I-III are also directed to different polypeptides that are physically and functionally distinct from one another. For example, the polypeptide in Group I is an isolated Apo-2 ligand polypeptide. The polypeptide in Group II is an isolated Apo-2 ligand polypeptide linked to polyethylene glycol. The polypeptide of Group III is a chimeric Apo-2 ligand polypeptide fused to a tag sequence. Each of the polypeptides in Groups I-III have a different structure and function and can be utilized in materially different methods, each without the other.

- b. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used as an antigen for the production of antibodies.
- c. Inventions II/III/IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups II/III/IV and V are unrelated products and method, wherein each is not required, one for another. For example, the isolated polypeptides of Inventions II/III cannot be used together with the claimed methods of Invention V because this invention does not recite the use or production of these polypeptides. The nucleic acid molecule of Invention IV cannot be used together with the claimed method of Invention V because this invention does not recite the use or production of this nucleic acid molecule.

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2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different search, different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

An isolated nucleic acid comprising DNA encoding the Apo-2 ligand polypeptide and a vector and host cell comprising the nucleic acid wherein the host cell is:

- a. CHO cell
- b. *E. coli*
- c. yeast cell

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10 and 18-26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If Applicant selects Group IV, one species from the type of host cell group must also be chosen to be fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bridget E. Bunner
Art Unit 1647
May 8, 2001



ELIZABETH KEMMERER
PRIMARY EXAMINER